

INSTALLATION QUALIFICATION REPORT

For the Metering Syringe Valve Leak Test System (TE0084040-2)

PREPARED BY

Name	Role	Signature	Date
Luo HuaZhen	Senior Test Engineer		24 Jun 2020

The "Prepared By" signature denotes that this document accurately describes the qualification activities.

REVIEWED BY

Name	Role	Signature	Date
Richard Davis	Principal Test Engineer		

The "Reviewed By" signature denotes agreement with the description of the qualification activities.

APPROVED BY

Name	Role	Signature	Date
Kah Chin TAN	Senior Quality Assurance Manager		

The "Approved By" signature denotes that this document has been reviewed and approved for overall quality and completeness.

REVISION HISTORY

VERSION:	00	ORIGINATOR:	Luo HuaZhen	Change ID:	N/A
SUMMARY OF CHANGE: First document for approval					

1.0 PURPOSE

The purpose of this Installation Qualification Report is to detail the activities associated with the execution of Test Specification and Procedure, MSV Leak Test 735004416, Rev A for the TE0084040-2, the Metering Syringe Valve Leak Test System.

1.1 SYSTEM BACKGROUND

The TE0084040-2, the Metering Syringe Valve Leak Test System, facilitates the functional test of the following part numbers: 289010714 and 289012763. These part numbers are functionally equivalent, the only difference being material (stainless steel versus titanium). They are tested by the system identically; therefore, the IQ was only performed using the 289010714 part number. Testing is achieved by running a leak test for each port to port configuration of the valve:

- Port 2 to 3: Inject Valve to Purge/Wash
- Port 1 to 3: Syringe to Purge/Wash
- Port 1 to 2: Syringe to Inject Valve.

The TE0084040-2, the Metering Syringe Valve Leak Test System is located at the Venture Contract Manufacturing Site in Singapore. The test system is comprised of a Micro BSM, Bronkhurst Flow Meter, and two selector valves alongside a test computer installed with custom software written in National Instruments LabVIEW. The Micro BSM is used to deliver flow and to set pressure within the fluidics of the test system. The selector valves are used to set the flow path through the correct UUT port and flow to waste/dead end the system. The leak rate is measured using the flow meter. A test fixture (999045028) is used to move the valve to each port to port fluid path. This fixture is manually operated by the test operator to position the valve in the correct path.

2.0 SCOPE

This Installation Qualification Report details the Qualification activities undertaken for the TE0084040-2, the Metering Syringe Valve Leak Test System, based on the requirements of the executed protocol, the Installation Qualification Protocol, 730004135 Ver. 03 as detailed in TE0084040-2-14APR20-VAF.

3.0 SUMMARY OF RESULTS – STATEMENT OF FITNESS FOR INTENDED USE

The TE0084040-2, the Metering Syringe Valve Leak Test System was tested in accordance with the Installation Qualification Protocol, 730004135 Ver. 03. All Test Scripts were performed, and all objective evidence requirements have been met.

Waters now has the necessary documentation in place to ensure that the TE0084040-2, the Metering Syringe Valve Leak Test System complies with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Qualification Report, the TE0084040-2, the Metering Syringe Valve Leak Test System can be considered fully qualified and fit for intended use.

4.0 DEFINITIONS / ABBREVIATIONS

The following definitions are used in this document:

Term	Explanation
cGMP	Current Good Manufacturing Practice
IQ	Installation Qualification
IQR	Installation Qualification Report
TSP	Test Specification and Procedure
CAL/PM	Calibration/Preventive Maintenance
S/N	Serial Number
P/N	Part Number
VAF	Validation Assessment Form
Hz	Hertz

Term	Explanation
N/A	Not Applicable
SAP	Enterprise Resource Planning Software
UUT	Unit Under Test
VAC	Volts Alternating Current
EQID	Equipment Qualification Identification
ANSI	American National Standards Institute
PSC	Production Support Checks
µL/min	Microliters Per Minute
BSM	Binary Solvent Manager
MSV	Metering Syringe Valve
UI	User Interface

5.0 TRAINING

The operator of the TE0084040-2, the Metering Syringe Valve Leak Test System was trained according to the Test Specification and Procedure, MSV Leak Test 735004416, Rev A. The executor of this qualification was trained to the Installation Qualification Protocol, 730004135 Ver. 03. Both Training records are provided as Attachments 7.1 and 7.2, respectively.

6.0 QUALIFICATION Results

- 6.1 Test Script IQ-01: Associated Documentation Verification was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.3.
 - 6.1.1 The Test Specification and Procedure, MSV Leak Test 735004416, Rev A was confirmed to be in SAP with a status of Release General. A screen capture from SAP is provided as Attachment 7.4.
- 6.2 Test Script IQ-02: Site Verification was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.5.
 - 6.2.1 The ambient temperature and humidity were measured using Temperature/Humidity Meter and were determined to be within specification as defined by the Performance Specification, 735004417, Rev 01. The calibration record is provided as Attachment 7.6.
 - 6.2.2 The electrical supply was measured using a Multimeter and was determined to be within specification as defined by ANSI C84.1 – Voltage Tolerance Standard. The calibration record is provided as Attachment 7.7.
 - 6.2.3 The Test Station was confirmed to have more than the four (4) dedicated electrical outlets and minimum of 1 dedicated network required.
 - 6.2.4 The space and test bench of the TE0084040-2, the Metering Syringe Valve Leak Test System were confirmed to have adequate space for testing and service. The bench was confirmed to be large and strong enough to support all test equipment. Picture of the Test Station work area is provided as Attachment 7.8.
- 6.3 Test Script IQ-03: Instrumentation Calibration Verification was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed script is provided as Attachment 7.9.
 - 6.3.1 The TE0084040-2, the Metering Syringe Valve Leak Test System was confirmed to be in the Preventive Maintenance Master Schedule with yearly maintenance cycle. A screen capture from the master list is provided as Attachment 7.10.
- 6.4 Test Script IQ-04: Software and Instrument Firmware Version was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.11.

- 6.4.1 The Test Equipment Software version listed in the TSP is Test Software 0.0 and was verified to match the version listed on the test equipment display. The objective evidence was provided as Attachment 7.12.
- 6.4.2 This test station does not download firmware.
- 6.5 Test Script IQ-05: General Safety and Alarms was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.13.
- 6.5.1 It was confirmed that there were no mechanical safety pinch points or sharp edges. Picture of tester station safety check is provided as Attachment 7.14
- 6.6 Test Script IQ-06: Functional Verification was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.15.
- 6.6.1 One (1) UUTs was tested using the TE0084040-2, the Metering Syringe Valve Leak Test System with all tests passing. The screenshot of passing result is provided as Attachment 7.16.
- 6.7 This table provides a summary of each test script as performed according to 730004135, Ver. 03 along with the attachment location of all objective evidence. The table also indicates any deviation taken from the scripts during qualification.

Script or Section	Pass/Fail	Objective Evidence	Deviations
IQ-01	Pass	Attachment 7.3 and 7.4	None
IQ-02	Pass	Attachments 7.5, 7.6, 7.7 and 7.8	None
IQ-03	Pass	Attachments 7.9 and 7.10	None
IQ-04	Pass	Attachments 7.11 and 7.12	None
IQ-05	Pass	Attachments 7.13 and 7.14	None
IQ-06	Pass	Attachments 7.15 and 7.16	None

7.0 ATTACHMENTS

- 7.1 Completed Operator Training Record 735004416, Rev A
- 7.2 Completed Executor Training Record 730004135, Ver. 03
- 7.3 Completed Test Script IQ-01: Associated Document Verification
- 7.4 Objective Evidence IQ-01: Screenshot of SAP
- 7.5 Completed Test Script IQ-02: Site Verification
- 7.6 Objective Evidence IQ-02: Temperature/Humidity Meter Calibration Record and Measurement Record
- 7.7 Objective Evidence IQ-02: Multimeter Calibration Record and Measurement Record
- 7.8 Objective Evidence IQ-02: Picture of Test Station Work Area
- 7.9 Completed Test Script IQ-03: Instrument Calibration Verification
- 7.10 Objective Evidence IQ-03: Screen Capture of Preventive Maintenance Master Schedule
- 7.11 Completed Test Script IQ-04: Test Software and Instrument Firmware Version
- 7.12 Objective Evidence IQ-04: Screenshot of test software version and Micro BSM firmware version
- 7.13 Completed Test Script IQ-05: General Safety and Alarms
- 7.14 Objective Evidence IQ-05: Picture of tester station safety check
- 7.15 Completed Test Script IQ-06: Functional Verification
- 7.16 Objective Evidence IQ-06: Screenshot of passing result on UUT

8.0 DEVIATION FROM THE QUALIFICATION PROTOCOL

There were no deviations generated during the execution of the Installation Qualification Protocol 730004135, Ver. 03.

9.0 References

The current approved versions of the following documents are referenced within this report:

Document Number	Document title
730004135, Ver. 03	Installation Qualification Protocol
735004416, Rev A	Test Spec and Procedure, MSV Leak Test
735004437, Rev A	Cal/PM TE0084040 MSV Leak Test System
735004417, Rev B	Metering Syringe Valve Subassembly Specification
WAT046538, Ver. 12	Generic Electrical Safety Test Procedure
ANSI C84.1	Voltage Tolerance Standard
TE0084040-2-14APR20-VAF	Validation Assessment Form for the Metering Syringe Valve Leak Test System

Appendix A: TRAINING RECORD

Document #	735004416	Document Title	TEST SPEC AND PROCEDURE, MSV LEAK TEST	Version	00
				Revision	A

Training Performed By: (If not used this section can be deleted)

N/A	N/A	N/A
Printed Name	Signature	Date

☒ Read and Understood (If self-trained – If not self-trained this section can be deleted)

By signing you acknowledge that you have reviewed, understand, and agree to comply with the policies and practices of the procedure defined above.

Printed Name	Signature	Initials	Date
Htay Ei Lwin	Htay Ei Lwin	Lwin	19 Jun 20

Print multiple copies of this Training Record Template as needed

Document No.: TE0084040-2-IQR
Iteration No.: 00
Attachment: 7.1 Page: 2 of 2

Title: individual Training Form

Document No: 730002657

Version No: 00

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Training Type:	Read and Understood		
Name:	Luo HuaZhen	Employee ID¹	618078
Date of Training	19SEP2019		
Comments:	N/A		

Document Number	Title	Rev. #
730004135	Installation Qualification Protocol	03


Senior Test Engineer
19SEP2018
 Employee's Signature Title Date

N/A Self Trained
JG 19SEP2019
 Trainer's Signature Title Date

¹ Without preceding "90"

Installation Qualification Protocol

Document # 730004135

Version # 03

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Test Script #	IQ-01	IQ Test Name:	Associated Documentation Verification	
Equipment #	TE0084040-2	Equipment Name:	METERING SYRINGE VALVE LEAK TESTER	
Installation Site: Venture Contract Manufacturing Site in Singapore				
Purpose: To verify that supporting documentation is available prior to the completion of qualification.				
Test Execution: - List all applicable documents (Preventive Maintenance, Calibration, Operating Procedures, Test Specification Procedures, Manufacturing Procedures, etc.) under the Document type header, then complete the table below. Rows may be added/removed as needed. - All applicable documents must have a status of Ready, Pre-Rel-Prod, or Release General in SAP. If applicable documents are unavailable in SAP state why in the comments section.				
Objective Evidence: - Completed IQ-01 Test Script Data Sheet - SAP screenshots of below available document(s)				
Document Type	Title, Doc. #, Version/Revision #		Status in SAP	Initial & Date
TSP	TEST SPEC AND PROCEDURE, MSV LEAK TEST 735004416, Rev A		RELEASE GENERAL	HZ 23 Jun 2020
CAL	Cal/PM TE0084040 MSV Leak Test System 735004437, Rev A		RELEASE GENERAL	HZ 23 Jun 2020
Comments: N/A				
Overall Test Conclusion			Document No.: TE0084040-2-IQR Iteration No.: 00 Attachment: 7.3 Page: 1 of 1	
☒ Pass ☐ Fail				

Attachment: 7.4 Page: 1 of 1

Installation Qualification Protocol

Document # 730004135

Version # 03

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Test Script #	IQ -02	IQ Test Name:	Site Verification		
Equipment #	TE0084040-2	Equipment Name:	METERING SYRINGE VALVE LEAK TESTER		
Installation Site: Venture Contract Manufacturing Site in Singapore					
Purpose: To verify the location in which the test equipment is to be installed is suitable for use. Test Execution: - List additional applicable parameters in the Parameters column. Rows may be added as needed. - Using the applicable equipment documentation, define the specification(s) in the Acceptance Criteria column. - Verify and/or measure the applicable parameters and complete the Table below. Do not delete any of the listed defined parameters. Enter N/A for any parameter or cell that is not used or applicable. The reason for why the parameter is not used or applicable shall be explained within the corresponding Installation Qualification Report. Objective Evidence: - Completed IQ-02 Test Script Data Sheet - Photo(s) of the work area, as applicable - The source of each Acceptance Criterion shall be referenced in the IQR if stored in SAP. If not in SAP objective evidence specifying the Acceptance Criterion shall be provided in or as an attachment to the IQR. - Copies of calibration certificates for measurement tools, if applicable					
Parameters	Acceptance Criteria	As Found	Pass/Fail	Initial & Date	
Ambient Temperature	18 °C to 28 °C	22.5 °C	Pass	HZ 23 Jun 2020	
Relative Humidity	10 % to 80 %, Non-Condensing	52.5%	Pass	HZ 23 Jun 2020	
Electrical Supply	100 VAC to 240 VAC, 50 Hz/60 Hz ±5%	220VAC, 49.98.Hz	Pass	HZ 23 Jun 2020	
Electrical Outlets	Minimum of 4 dedicated outlets	8 outlets	Pass	HZ 23 Jun 2020	
Network Available	Minimum of 1 dedicated network	1 network	Pass	HZ 23 Jun 2020	
Workspace	The system has sufficient room for the test station, UUT and service		Pass	HZ 23 Jun 2020	
Test Station Bench	The Test Station Bench is large and strong enough to support the station		Pass	HZ 23 Jun 2020	
Comments: - Ambient temperature/humidity measured using a Temperature/Humidity Meter, Control Number AA13015316. - Electrical supply measured using a Multimeter, Control Number 23372873 Note: If the electrical supply range or tolerance is not specified for voltage and/or frequency, a tolerance of ±5% may be used in accordance with ANSI C84.1 – Voltage Tolerance Standard.					
Overall Test Conclusion			Document No.: TE0084040-2-IQR Iteration No.: 00 Attachment: 7.5 Page: 1 of 1		
☒ Pass ☐ Fail					

**BESTLABS SINGAPORE**

PTE LTD.

CO REG NO : 201728718W

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CERTIFICATE NO. : BLT2001908-1

PAGE 1 OF 2

SUBMITTED TO :
GES (Singapore) Pte Ltd
28 Marsiling Lane
Singapore 739152

REFERENCE NO. : BSO-20-001908

RECEIVED DATE : 16-Mar-2020



Bestlabs organization and practices have been duly accredited and are compliant to the requirements of ISO 9001.

The reference measurement standards used are traceable to National Metrology Centre,(NMC,SINGAPORE) and/or other National Standards.

INSTRUMENT	ALARM THERMOHYGROMETER				
MANUFACTURER	DR SENSOR	AMB. TEMPERATURE	(21 ± 2) °C		
MODEL NO.	HT-5B	RELATIVE HUMIDITY	(55 ± 10) % relative humidity		
SERIAL NO.	AA13015316	CALIBRATED DATE	17-Mar-2020		
RANGE	(-20~50°C) / (10~90) %rh	DUE DATE	16-Mar-2021		
TAG NO.	W1-16GP0075	-	-		
PART NO.	-	-	-		
LOCATION	-	-	-		
CALIBRATION AT	BLS Laboratory	-	-		

MEASUREMENT TRACEABILITY

REFERENCE STANDARDS	TRACEABILITY	SERIAL NO.	TAG NO.	CAL. DATE	DUE DATE
THERMOHYGROMETER	NMC SINGAPORE	61478840/2008169	BS 1516	02-Jul-2019	01-Jul-2020

METHOD OF CALIBRATION: FST 11

NOTES:

- The results of the calibration are given on the attached following pages.
- The expanded uncertainty of measurement associated with the calibration is estimated at a confidence level of approximately 95%.
- No adjustment was done unless otherwise stated.
- The user should determine the suitability of the instrument for its intended use.
- The reports shall not be reproduced except in full, without written approval by management representative of BESTLABS SINGAPORE PTE LTD.
- The calibration was performed in a controlled temperature & humidity source.

Document No.: TE0084040-2-IQR

Iteration No.: 00

Attachment: 7.6 Page: 1 of 2

R RAMESH | ASST. TECHNICAL MANAGER
CALIBRATION OFFICER25702864
23-MAR-2020S KARUPPIAH | TECHNICAL MANAGER
APPROVING OFFICER

**BESTLABS SINGAPORE**

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CERTIFICATE NO. : BLT2001908-1

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TEST RESULTS :

REFERENCE READING	INSTRUMENT READING		CORRECTION	EXPANDED UNCERTAINTY	COVERAGE FACTOR
	BEFORE ADJ.	AFTER ADJ.			
RELATIVE HUMIDITY @50% relative humidity UNIT: °C					(K)
10.1	10.4	-	-0.3	0.49	2.00
20.2	20.6	-	-0.4	0.49	2.00
30.3	30.7	-	-0.4	0.58	2.00
40.4	40.8	-	-0.4	0.58	2.00
50.4	50.8	-	-0.4	0.92	2.00
RELATIVE HUMIDITY @21°C UNIT: % relative humidity					(K)
20.4	19.7	-	0.7	3.4	2.00
30.6	29.6	-	1.0	3.4	2.00
40.5	39.4	-	1.1	3.5	2.00
51.2	50.1	-	1.1	3.5	2.00
61.4	60.2	-	1.2	3.8	2.00
72.1	70.9	-	1.2	3.8	2.00
83.3	81.0	-	2.3	3.8	2.00
92.7	89.9	-	2.8	4	2.00

***** End Of Test Results *****

Document No.: TE0084040-2-IQR

Iteration No.: 00

Attachment: 7.6 Page: 2 of 2

MULTIMETER CALIBRATION REPORT

Equipment : Multimeter Cal Date : 02 / Jan / 2020
Brand Name : FLUKE Next Cal Date : 02 / Jan / 2021
Model : FLUKE 115 Environment Cond. : N.A.
GES/Mfg Serial No. : 23372873 Equipment Used : Yokogawa Portable Calibrator
Cal Procedure : WI-QMS-044 S/No. 2422

Calibration Data

Calibrator Output	Accuracy		Measured Reading (before)	Measured Reading (after)
	Digital	Analog		
300 mV	297.9 ~ 302.1 mV	270.0 ~ 330.0 mV	300.2	N.A.
3 V	2.979 ~ 3.021 V	2.700 ~ 3.300 V	2.999	N.A.
30 V	29.79 ~ 30.21 V	27.00 ~ 33.00 V	29.99	N.A.
20 mA	19.86 ~ 21.14 mA	18.00 ~ 22.00 mA	NA	N.A.

Result : Pass / Fail

Remarks : Multimeter is tested ok within calibration range and Multimeter is not used to test current.

Calibrated by

Name/sign : Lee Kwang Quek
Designation : Senior Technician
Date : 02-Jan-2020

Reviewed by

Name/sign : Sheliyan Sathivelu
Designation : Senior QA Engineer
Date : 02 Jan 2020

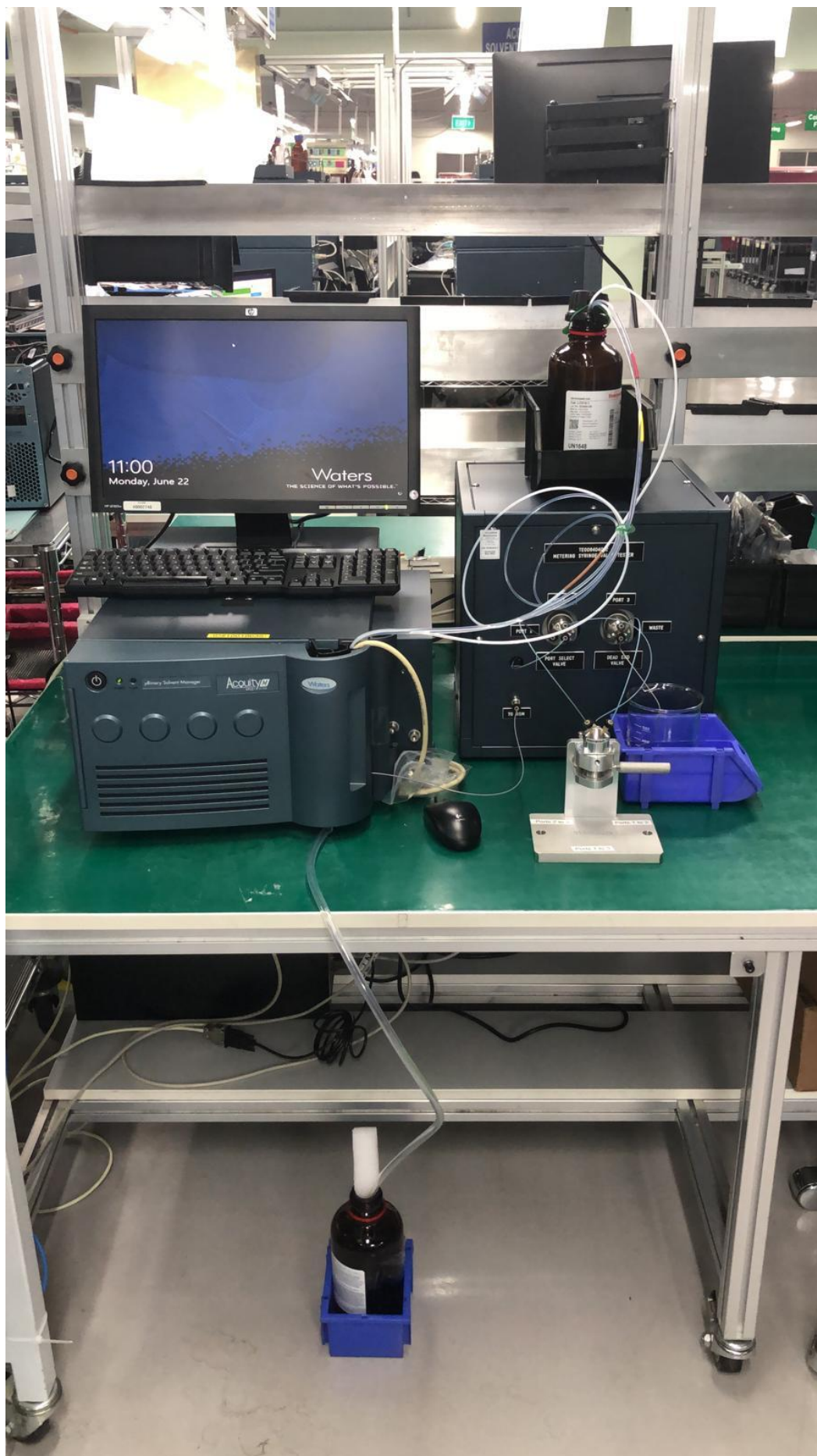
Document No.: TE0084040-2-IQR

Iteration No.: 00

Attachment: 7.7 Page: 1 of 1

IQ-02 Site Verification

Adequate space for testing and service



Document No.: TE0084040-2-IQR

Iteration No.: 00

Attachment: 7.8 Page: 1 of 1

Installation Qualification Protocol

Document # 730004135

Version # 03

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Test Script #	IQ-03	IQ Test Name:	Instrumentation Calibration Verification	
Equipment #	TE0084040-2	Equipment Name:	METERING SYRINGE VALVE LEAK TESTER	
Installation Site:	Venture Contract Manufacturing Site in Singapore			
Purpose: To verify that all critical instruments are in the calibration database and that a calibration and/or a preventive maintenance has been performed, as appropriate. Test Execution: - List all critical instruments/components and/or sub-systems that require calibration and/or preventive maintenance in the Description column. Rows may be added as needed. - Verify that all listed critical instruments/components have had a preventive maintenance and/or calibration performed in accordance with the PM and/or Calibration procedure(s) or by an outside source, and are listed within the associated calibration database, then complete the table below. Objective Evidence: - Completed IQ-03 Test Script Data Sheet - Copies of calibration and/or maintenance certificates - Screen captures from the associated Calibration database				
Description	Asset #	Cal/PM Dates	Initial & Date	
TE0084040-2	TE0084040-2	Last Cal/PM: 25 Mar 2020 Cal/PM Due: 25 Mar 2021	HZ 23 Jun 2020	
Micro Binary Solvent Manager	E14NIB091R	Last Cal/PM: 25 Mar 2020 Cal/PM Due: 25 Mar 2021	HZ 23 Jun 2020	
Comments: This a newly transferred tester from Waters Milford; Last maintenance was done in Milford. A screen capture of PM/Calibration Master List showing both have been scheduled.				
Overall Test Conclusion		Document No.: TE0084040-2-IQR Iteration No.: 00 Attachment: 7.9 Page: 1 of 1		
☒ Pass ☐ Fail				

Waters consigned equipment, Total : 103 items (Without Payment)
Date : 23-JUN-2020

81	WATERS	W1-17GC0115	Acquity CPSM Final Test System	WATERS	LENOVO	TE83064-13	VENTURE	12	16/09/2019	16/10/2020	Consigned equipment
82	WATERS	W1-17GC0116	Acquity CPSM Final Test System	WATERS	LENOVO	TE83064-14	VENTURE	12	18/12/2019	18/12/2020	Consigned equipment
83	WATERS	W1-17GC0117	Acquity CPSM Final Test System	WATERS	LENOVO	TE83064-15	VENTURE	12	16/01/2019	16/01/2020	Consigned equipment
84	WATERS	W1-17GC0118	Acquity CPSM Final Test System	WATERS	LENOVO	TE83064-16	VENTURE	12	16/12/2019	16/12/2020	Consigned equipment
85	WATERS	W1-17GC0119	Acquity CPSM Final Test System	WATERS	LENOVO	TE83064-17	VENTURE	12	18/12/2019	18/12/2020	Consigned equipment
86	WATERS	W1-17GC0120	Unit Serial Number Label Printer	WATERS	LAC/E 32	WATERSISNL1	VENTURE	12	03/04/2019	03/04/2020	Consigned equipment
87	WATERS	W1-17GC0121	Certificate Printer	WATERS	LAC/E 32	WATERSCOFP1	VENTURE	12	03/04/2020	03/04/2021	Consigned equipment
88	WATERS	W1-18GC0141	QDA TEST BAY 01	WATERS	N/A	QDA TEST BAY 01	VENTURE	12	28/11/2019	28/11/2020	Consigned equipment
89	WATERS	W1-18GC0142	QDA TEST BAY 02	WATERS	N/A	QDA TEST BAY 02	VENTURE	12	27/11/2019	27/11/2020	Consigned equipment
90	WATERS	W1-18GC0143	QDA TEST BAY 03	WATERS	N/A	QDA TEST BAY 03	VENTURE	12	27/11/2019	27/11/2020	Consigned equipment
91	WATERS	W1-18GC0144	QDA TEST BAY 04	WATERS	N/A	QDA TEST BAY 04	VENTURE	12	27/11/2019	27/11/2020	Consigned equipment
92	WATERS	W1-19GC0151	Leak Detector	Leybold	PhoenixL 300i	90001370779	VENTURE	12	09/03/2020	09/03/2021	Consigned equipment
93	WATERS	W1-19GC0156	QDA TEST BAY 05	WATERS	N/A	QDA TEST BAY 05	VENTURE	12	01/04/2019	01/04/2020	Consigned equipment
94	WATERS	W1-19GC0157	QDA TEST BAY 06	WATERS	N/A	QDA TEST BAY 06	VENTURE	12	01/04/2019	01/04/2020	Consigned equipment
95	WATERS	W1-19GC0158	QDA TEST BAY 07	WATERS	N/A	QDA TEST BAY 07	VENTURE	12	01/04/2019	01/04/2020	Consigned equipment
96	WATERS	W1-19GC0159	QDA TEST BAY 08	WATERS	N/A	QDA TEST BAY 08	VENTURE	12	01/04/2019	01/04/2020	Consigned equipment
97	WATERS	W1-19GC0187	Detector Final Test Station	WATERS	186008877	TE82760-7	VENTURE	12	23/12/2019	23/12/2020	Consigned equipment
98	WATERS	W1-19GC0188	1525 Binary HPLC Pump	WATERS	186001525	C1525P993A	FLEXTRONICS	12	28/04/2020	28/04/2021	Consigned equipment
99	WATERS	W1-19GC0189	ALLIANCE COLUMN HEATER/COOLER	WATERS	LAC/E 32	TE82774-4	VENTURE	12	05/08/2019	05/08/2020	Consigned equipment
100	WATERS	W1-20GC0190	INTEGRATED SYSTEM TEST STATION	WATERS	NA	TE0084054-3	VENTURE	12	26/05/2020	26/05/2021	Consigned equipment
101	WATERS	W1-20GC0191	INTEGRATED SYSTEM TEST STATION	WATERS	NA	TE0084054-4	VENTURE	12	26/05/2020	26/05/2021	Consigned equipment
102	WATERS	W1-20GC0192	Metering Syringe Valve Leak Tester	WATERS	NA	TE0084040-2 (ID#10018635)	VENTURE	12	25/03/2020	25/03/2021	Consigned equipment
103	WATERS	W1-20GC0193	Micro Binary Solvent Manager	WATERS	800000444	E14NIB091R	VENTURE	12	25/03/2020	25/03/2021	Consigned equipment

Prepared by Venture
Name : Chua Chong Keong
Signature :
Designation : Manufacturing Engineer
Date : 23-Jun-2020

Document No.: TE0084040-2-IQR

Iteration No.: 00

Attachment: 7.10 Page: 1 of 1

Installation Qualification Protocol

Document # 730004135

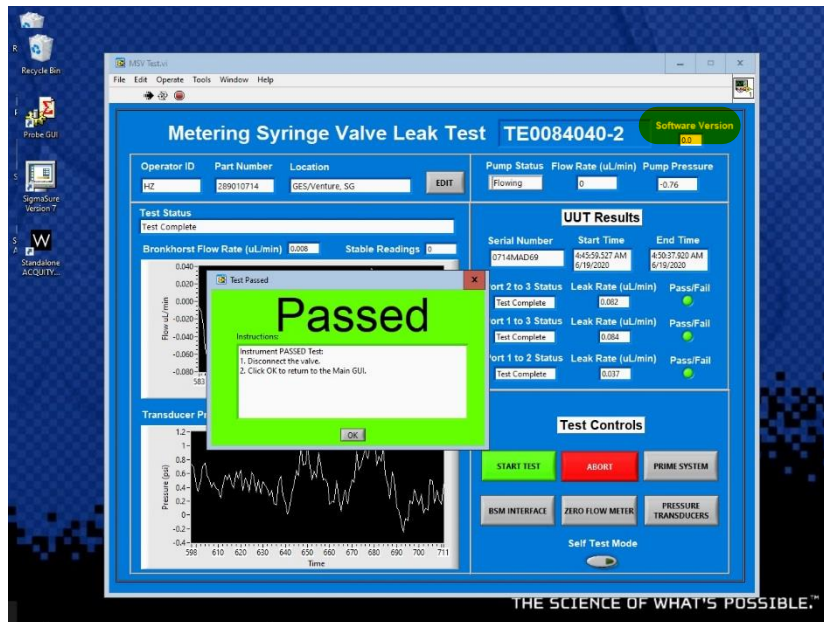
Version # 03

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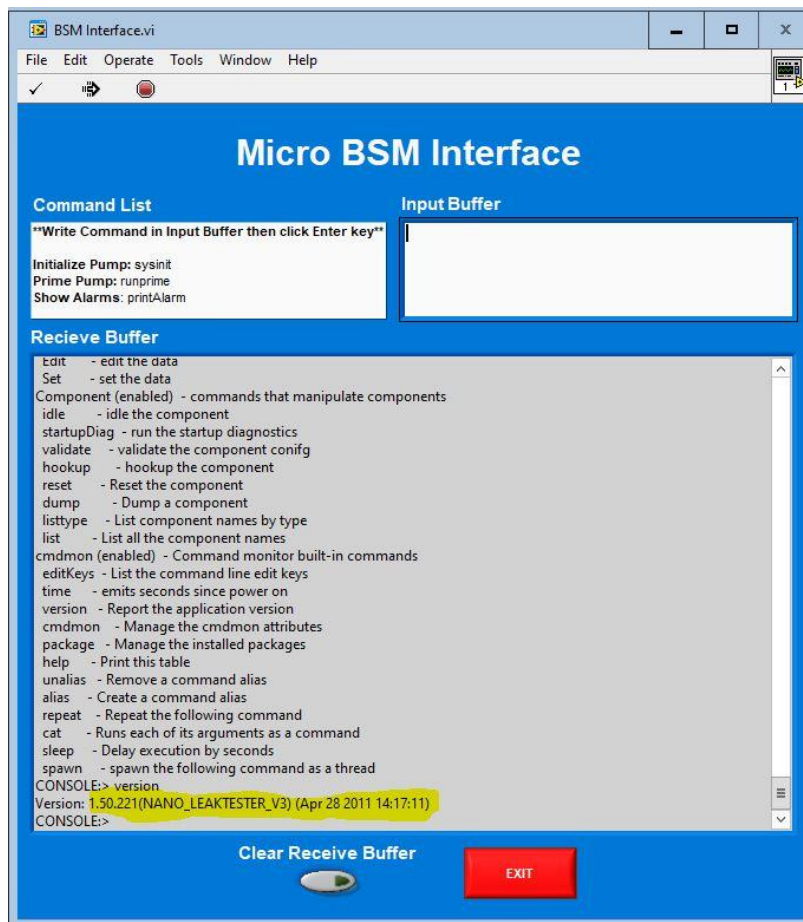
Test Script #	IQ-04	IQ Test Name:	Test Software and Instrument Firmware Version		
Equipment #	TE0084040-2	Equipment Name:	METERING SYRINGE VALVE LEAK TESTER		
Installation Site: Venture Contract Manufacturing Site in Singapore					
Purpose: To verify that the installed software/firmware is correct per the applicable design and/or operational document(s). Test Execution: - List all relevant Equipment software and/or instrument firmware in the Description column. Specify the associated part number for the instrument firmware, if applicable. Rows may be added/removed as needed. - List the associated required equipment software and/or critical instrument/internet connection sharing firmware version(s), as defined in the applicable design/operational document(s), in the Acceptance Criteria column. - Verify that the software version displayed on the Operator Interface of the program and/or the firmware loaded on the instruments/PC match the acceptance criteria identically, if applicable, then complete the table below. Objective Evidence: - Completed IQ-04 Test Script Data Sheet - Identify and/or provide a screen capture/print out/copy of the applicable design/operational document that defines the required software/firmware version(s) within or as an attachment to the associated Installation Qualification Report. - Screen capture and/or test record displaying/indicating the software and/or firmware version(s), as applicable					
Description	Acceptance Criteria	As Found	Pass/Fail	Initial & Date	
Test Equipment Software	Version: 0.0	Version:	0.0	HZ 23 Jun 2020	
Micro Binary Solvent Manger Firmware	Version: 1.50.221	Version:	1.50.221	HZ 23 Jun 2020	
Comments: N/A					
Overall Test Conclusion			Document No.: TE0084040-2-IQR Iteration No.: 00 Attachment: 7.11 Page: 1 of 1		
☒ Pass ☐ Fail					

IQ-04 Test Software and Instrument Firmware Version

Screenshot of Test Software showing Version 0.0



Screenshot of BSM interface showing Micro BSM Firmware Version 1.50.221.



Document No.: TE0084040-2-IQR

Iteration No.: 00

Attachment: 7.12 Page: 1 of 1

Installation Qualification Protocol

Document # 730004135

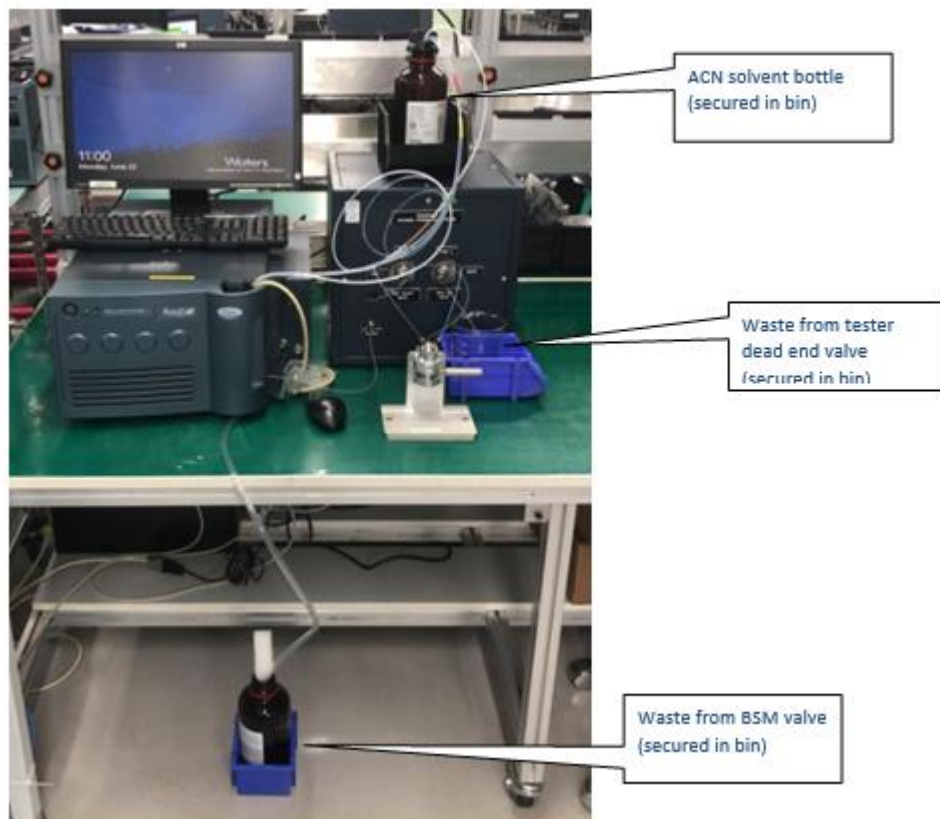
Version # 03

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Test Script #	IQ-05	IQ Test Name:	General Safety and Alarms	
Equipment #	TE0084040-2	Equipment Name:	METERING SYRINGE VALVE LEAK TESTER	
Installation Site: Venture Contract Manufacturing Site in Singapore				
Purpose: To verify that the equipment can operate in a safe manner, within its designated location. Test Execution: - List any additional safety related conditions or alarms in the Safety Inspection column, such as: guarding, interlocks, thermal or mechanical safety, chemical, secured gas tanks, restart or power loss, emergency stop, environmental exhaust, electrical safety, noise, safety labels, etc. Rows may be added as needed. EH&S shall be consulted as necessary. - List the associated safety requirement(s)/specification(s) in the Acceptance Criteria column. - Perform an inspection/test of the equipment to assess its safety related conditions, then complete the table below. Objective Evidence: - Completed IQ-05 Test Script Data Sheet - Photo(s) of the secured glass bottles, tanks, etc., if applicable - The source of any applicable Acceptance Criterion shall be summarized in the IQR if stored in SAP. If the source is not stored in SAP, at a minimum the page specifying the applicable Acceptance Criterion shall be provided as an attachment.				
Safety Inspection		Acceptance Criteria	Pass/Fail	Initial & Date
Mechanical Safety/ Pinch Points/Sharp Edges		None Found (or mitigated appropriately)	Pass	HZ 23 Jun 2020
Glass Bottles		Secure	Pass	HZ 23 Jun 2020
Waste Tanks		Secure and located below the system	Pass	HZ 23 Jun 2020
Emergency Stop		System ceases operation upon depressing the Emergency Stop button	N/A	HZ 23 Jun 2020
Guarding		Shielding in place to prevent hazard during operation	N/A	HZ 23 Jun 2020
Comments: N/A				
Overall Test Conclusion			Document No.: TE0084040-2-IQR Iteration No.: 00 Attachment: 7.13 Page: 1 of 1	
☒ Pass ☐ Fail				

IQ-05 General Safety and Alarms

Solvent bottle and waste tank are secured.



Document No.: TE0084040-2-IQR

Iteration No.: 00

Attachment: 7.14 Page: 1 of 1

Installation Qualification Protocol

Document # 730004135

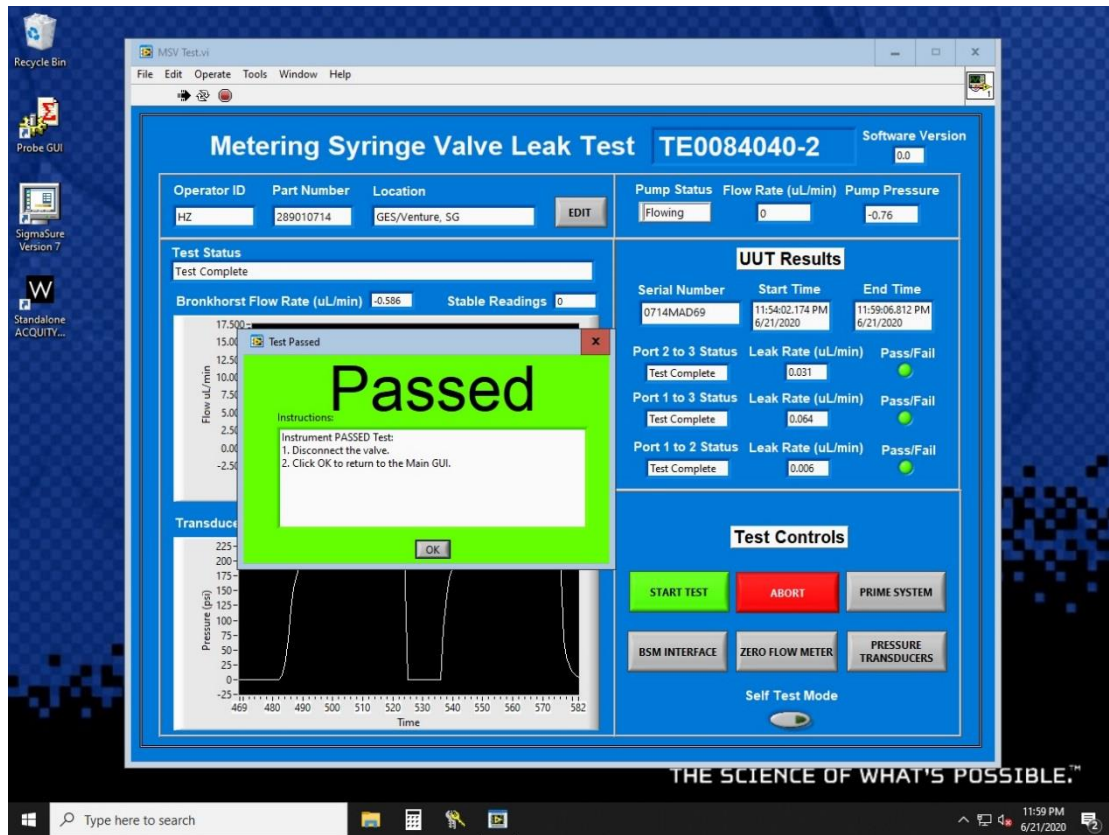
Version # 03

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Test Script #	IQ-06	IQ Test Name:	Functional Verification	
Equipment #	TE0084040-2	Equipment Name:	METERING SYRINGE VALVE LEAK TESTER	
Installation Site: Venture Contract Manufacturing Site in Singapore				
Purpose: To verify that the system operates as expected. Test Execution: - Select the UUT(s) or tests to be performed as defined within the Installation Qualification Section of 730001835. - List the Part Number and Serial Number, if applicable, in the UUT Part Number/Serial Number column. - Define the appropriate Acceptance Criteria within the Acceptance Criteria column. - Perform a test of the UUT(s), verify the Acceptance Criteria, then complete the table below. If an associated Test Record is being used as objective evidence the Header/Footer information should be verified for accuracy. Objective Evidence: - Completed IQ-06 Test Script Data Sheet - Copy of the Test Record(s) for the UUT(s), as applicable - The UUT(s) selected for this Test Script and the reasoning for why it/they were selected shall be summarized within the associated Installation Qualification Report. - If this Acceptance Criteria is other than "All required CTQ Specification measurements result in a Pass" then it shall be summarized within the associated VAF, Process Validation Plan, and/or Installation Qualification Report. - For systems that download firmware to product the BOM showing the firmware requirement shall be provided within the IQR.				
UUT Part Number/Serial Number		Acceptance Criteria	Pass/Fail	Initial & Date
Part Number: 289010714 Serial Number: D174MAD69		All required CTQ Specification measurements result in a Pass	Pass	HZ 23 Jun 2020
Comments: N/A				
Overall Test Conclusion			Document No.: TE0084040-2-IQR Iteration No.: 00 Attachment: 7.15 Page: 1 of 1	
☒ Pass ☐ Fail				

IQ-06 Functional Verification

Screenshot of Test Software showing Passing Result of functionality check



Document No.: TE0084040-2-IQR

Iteration No.: 00

Attachment: 7.16 Page: 1 of 1